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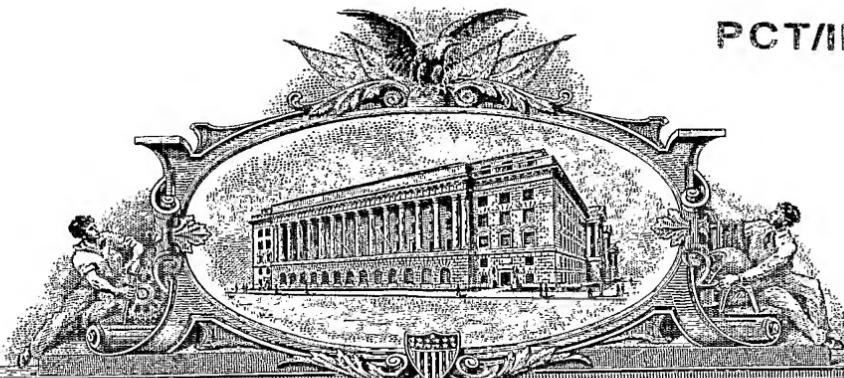
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**APPLICATION NUMBER: 60/520,672****FILING DATE: November 18, 2003**

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This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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INVENTOR(S)					
Given Name (first and middle (if any))		Family Name or Surname		Residence (City and either State or Foreign Country)	
1) Steven R.		ROGERS		D.N. Emek Sorek, ISRAEL	
Additional inventors are being named on the <u>2ND</u> separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
MEASUREMENT SYSTEM AND METHOD FOR USE IN DETERMINING THE PATIENT'S CONDITION					
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Respectfully submitted,

[Page 1 of 2]

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SIGNATURE

REGISTRATION NO. 47,421

TYPED or PRINTED NAME Marvin C. Berkowitz

(if appropriate)

Docket Number: 25841

TELEPHONE 202-775-8383

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INVENTOR(S)/APPLICANT(S)		
Given Name (first and middle [if any] )	Family or Surname	Residence (City and either State or Foreign Country)
2) Allon	LEIBOVITZ	Shoham, ISRAEL
3) Menashe	SHAHAR	Drom Hagolan, ISRAEL
4) Eliezer	DESHEN	D.N. Emek Sorek, ISRAEL

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## **MEASUREMENT SYSTEM AND METHOD FOR USE IN DETERMINING THE PATIENT'S CONDITION**

### **FIELD OF THE INVENTION**

This invention relates to an optical measurement system and method, as well as an optical probe to be utilized in such system, for use in determining the patient's condition, particularly for the ear condition.

### **5 BACKGROUND OF THE INVENTION**

Non-invasive optical measurements on a patient's body have been developed and are disclosed for example in the following patent publications: US 4,882,492; US 5,001,556; US 5,280,788; US 5,379,764; US 5,582,168; US 6,230,044; US 6,319,199; US 6,379,920; and WO 99/66830. The technique suitable  
10 for the diagnosis of ear-related diseases, such as otitis media, is disclosed in WO 02/39874 assigned to the assignee of the present application.

Optical measurements on the patient's ear employ an optical probe such as an otoscope, in which the ear canal is illuminated via a suitable light source. The physician can then view the image directly via an eyepiece mounted to the  
15 otoscope, or via a video image, as in US 5,919,130 or US 5,363,839. For reasons of sterility or hygiene and convenience, it is usually appropriate to cover the optical probe with a removable sheath or speculum that prevents contamination to or from the probe, and thus enables the same probe to be used with many patients without the need for sterilizing or disinfecting the probe itself between patients. Typically,  
20 the sheath is disposable, and thus made from a low-cost material, thus avoiding the need to sterilize or disinfect the sheath itself after use.

In more advanced systems it may be desirable to improve the quality of the light that is captured from the tissue being investigated, for example the ear canal or the vaginal walls, for the purpose of enhancing the sensitivity of subsequent analyses on this light. In WO 00/74556, for example, an optical probe is provided  
5 having an accessory device comprising an integral light-focusing element that enhances the light transmitting functions of the probe, and a window may be provided that acts as an objective for the probe's illumination elements. The accessory device may comprise optical elements such as a system of internal mirrors coupled to the window, or a toroidal ring segment in the form of an annular  
10 lens, that allow the device to act as a waveguide to direct light onto target tissues. While the light focusing effect achieved by these arrangements indirectly enhances visualization or data collection, it does not provide a simple and effective mechanism to maximize the quality of transmission of the light reflected or refracted by the tissues via the accessory device itself.

## 15 SUMMARY OF THE INVENTION

There is a need in the art to facilitate optical measurements on the patient's body by providing novel method and system that enable automatic identification of the patient's condition from measured spectral data.

According to one broad aspect of the present invention, there is provided a  
20 measurement system for use in determining a patient's condition, the system comprising:

- (a) an optical measuring unit operable for applying spectral measurements to the region of interest in a patient's body with predetermined light spectrum and producing measured spectral data indicative thereof; and
- 25 (b) a control unit for receiving and processing the measured data to generate output data indicative of the measurement results, the control unit comprising a memory utility for storing predetermined reference data representative of a value or a range of values for at least one predetermined measurable parameter corresponding to a healthy condition of a patient; a

data processing and analyzing utility preprogrammed for processing and analyzing the measured data by selecting a certain part of the measured data within at least one range of the predetermined light spectrum and applying a predetermined model to the selected part of the measured data to determine a corresponding value of said at least one predetermined measurable parameter for the measured patient and to generate said output data indicative of association between the determined parameter value and the reference data.

Preferably, the processing of the measured spectral data comprises normalizing the measured spectral data to thereby obtain a relative spectrum. The predetermined model is then applied to the relative measured spectrum.

The normalization of the measured spectral data includes normalization by a reference spectrum, and preferably also normalization by a certain wavelength from the predetermined light spectrum. The result of normalizing the measured data by the reference spectrum is a normalized reflectivity spectrum.

The reference spectrum is indicative of the light intensity illuminating the region of interest as a function of wavelengths of said predetermined incident light. Generally, this can be implemented by operating the measuring unit to apply spectral measurements to a highly reflective (preferably highly diffusedly reflective) surface. Preferably, this is achieved by appropriately configuring the measuring unit, for example, by providing a plug that has a highly diffusedly reflective surface and is mounted on the measuring unit such that it is shiftable from its operative position when said surface is located in the optical path of light propagating through the measuring unit and an inoperative position of the plug when said surface is out of the optical path of said light. Hence, the measuring unit can be operated to selectively obtain the reference spectrum or the measured data.

Generally, the at least one selected range of the predetermined light spectrum is defined by the patient's condition to be detected. For example, for the purposes of determining the existence of otitis media condition in the patient's ear,

the predetermined light spectrum is preferably within 300-1100nm. The selected spectrum preferably includes a range of 500-650nm, and/or a range of 800-950nm.

The data processing with the predetermined model preferably includes: applying a Likelihood Algorithm to the relative measured spectrum, calculating a feature vector as a function of wavelength within the selected range, and calculating a log-likelihood ratio between the feature vector of the relative measured spectrum and that of the reference data. This ratio is scalable to determine the at least measurable parameter indicative of the patient's condition. Preferably, the control unit is configured as an expert system capable of periodically analyzing the calculated measurable parameters and optimizing the model accordingly.

Preferably, the processing of the relative measured spectrum allows for determining two measurable parameters indicative of the existence in the patient's ear of, respectively, serous otitis media (SOM) and acute otitis media (AOM).

The normalizing of the measured spectral data by the reference spectrum may be carried out by presenting the measured spectrum  $E_j(\lambda, t)$  and the reference spectrum  $W_j(\lambda, t)$  as, respectively,

$$E_j(\lambda, t) = A I_j(\lambda, t) R_E(\lambda) D_j(\lambda, t) \text{ and } W_j(\lambda, t) = B I_j(\lambda, t) R_W(\lambda) D_j(\lambda, t)$$

wherein  $j$  is the number of the measuring unit,  $t$  is the time,  $\lambda$  is the wavelength of incident light,  $A$  and  $B$  are unknown amplitudes,  $I_j(\lambda, t)$  is the illumination spectrum of light source for the measuring unit  $j$ ;  $D_j(\lambda, t)$  is the light response spectrum of a detector assembly of for measuring unit  $j$ ;  $R_E(\lambda)$  is the reflectivity spectrum of the region of interest; and  $R_W(\lambda)$  is the reflectivity of a reference surface used in obtaining said reference spectrum, the normalized reflectivity spectrum being thus determined as:

$$R(\lambda) = E_j(\lambda, t) / W_j(\lambda, t) = C R_E(\lambda) / R_W(\lambda),$$

wherein parameter  $C$  is a light signal amplitude depending *inter alia* upon a signal integration time and a distance between the measuring unit and the region of interest.

The normalized reflectivity spectrum can be further normalized by a certain wavelength  $\lambda_0$  within the selected spectrum range, such that all the light intensities are measured relative to the intensity at wavelength  $\lambda_0$ . Hence, the effect of

parameter  $C$  can be eliminated. This can be implemented by setting a relative spectrum  $r(\lambda) = R(\lambda) / R(\lambda_0)$  so that  $r(\lambda_0) = 1$ . The selected value of  $\lambda_0$  is the center of the wavelength range of the predetermined incident light.

Preferably, the creation of the reference data and the model includes  
 5 sampling a spectrum  $r(\lambda)$  at certain discrete wavelengths, to generate a feature vector  $\underline{r} = \{ r(\lambda_n), n = 1, 2 \dots N \}$ ; learning probability densities  $f(\underline{r} | A)$  and  $f(\underline{r} | B)$  for populations including (A) healthy ears and (B) infected ears; and defining the value or range of values as a threshold  $T1$  chosen to achieve a desired level of sensitivity corresponding to the probability of correctly diagnosing the existence of  
 10 the predetermined condition of the patient's ear. The probability densities may for example include Gaussian probability densities  $f(\underline{r} | A) = g(\underline{r}, \underline{\mu}_A, P_A)$  and  $f(\underline{r} | B) = g(\underline{r}, \underline{\mu}_B, P_B)$ , wherein  $g(\underline{r}, \underline{\mu}, P) = [2\pi \det(P)]^{-N/2} \exp[-1/2 (\underline{r} - \underline{\mu})^T P^{-1} (\underline{r} - \underline{\mu})]$ ,  $\underline{\mu} = \text{mean}(\underline{r})$ ,  $P = \text{covariance}(\underline{r}) = N \times N$  matrix. The measured feature vector is then processed to determine the log-likelihood ratio as

$$\begin{aligned} 15 \quad L1(\underline{x}) &= 2 \log \{ f(\underline{x} | B) / f(\underline{x} | A) \} \\ &= (\underline{x} - \underline{\mu}_A)^T P_A^{-1} (\underline{x} - \underline{\mu}_A) - (\underline{x} - \underline{\mu}_B)^T P_B^{-1} (\underline{x} - \underline{\mu}_B) \end{aligned}$$

Then, the association between this ratio and the predetermined threshold value  $T1$  is determined which is indicative of the existence of the otitis media in the patient's ear.

20 The technique of the present invention provides for identifying whether the otitis media includes serous otitis media (SOM) or acute otitis media (AOM). To this end, the creation of the reference data and the model includes defining the value or range of values as a threshold  $T2$  chosen to achieve a desired level of sensitivity corresponding to the probability of correctly diagnosing the existence of  
 25 (B1) the serous otitis media (SOM) and (B2) acute otitis media (AOM). The measured feature vector is processed to determine the log-likelihood ratio as:

$$\begin{aligned} L2(\underline{x}) &= 2 \log \{ f(\underline{x} | B2) / f(\underline{x} | B1) \} \\ &= (\underline{x} - \underline{\mu}_{B1})^T P_{B1}^{-1} (\underline{x} - \underline{\mu}_{B1}) - (\underline{x} - \underline{\mu}_{B2})^T P_{B2}^{-1} (\underline{x} - \underline{\mu}_{B2}), \end{aligned}$$

and then the association between the ratio L2 and the predetermined threshold value T2 is determined being indicative of whether the detected otitis media is SOM or AOM.

5 Additionally, the technique of the present invention allows for conducting qualitative measurements at the same time as allowing the user (physician) to observe the target tissue itself. This is implemented by configuring the measuring unit (an optical probe) for transmitting light emanating from a target tissue (region of interest) along at least two separate optical channels. The probe comprises a probe head and a speculum member removably fitted to a distal end of the probe  
10 head. The probe head comprises light transmission means for directing an illuminating light to said target tissue via a distal end of the speculum, and means for directing light emanating from the target tissue along at least two separate optical channels. The speculum member is adapted for positioning the distal end thereof proximate to the target tissue. The distal end of the speculum member  
15 comprises an optical aperture for enabling illuminating light and emanating light to pass therethrough from and to the optical probe. The at least two separate optical channels comprise a first channel for enabling qualitative analysis of said light emanating from said target tissue, and a second channel for enabling quantitative analysis of said light emanating from said target tissue.

20 Preferably, the speculum member comprises an internal reflecting mirror for directing illuminating light from the light transmission means to said distal end. The probe head comprises a beam splitter arrangement for splitting light traveling in a proximal direction from said distal end into said first channel and said second channel. The term "beam splitter arrangement" refers herein to any optical  
25 arrangement capable of splitting a light beam into at least two beams, i.e., two channels or directions, substantially unaffected the intensity or wavelength of the light. Preferably, the beam splitter arrangement comprises a parabolic mirror having an aperture therein. Alternatively, the aperture may be replaced with a plug of transparent material, which preferably non-diffracting. The aperture is configured  
30 for directing a first portion of light traveling from said distal end therethrough along

the first channel and towards an objective. The latter may comprise an eyepiece ocular, or a suitable camera means for recording said image. The parabolic mirror may comprise an optical focusing element for directing a second portion of said light traveling from said distal end along said second channel and towards a light  
5 sensor.

Alternatively, or additionally, the speculum member may comprise a suitable first waveguide for directing illuminating light from said light transmission means to said distal end. The first waveguide is in the form of a first layer of material having waveguiding properties comprised in said speculum member, and the first  
10 layer having a transmitting face proximate to said distal end, and a first mating face in optical communication with said transmitting face and adapted for enabling illumination light from said light transmission means to pass therethrough to said transmitting face when said speculum member is fitted to said probe head. The light transmission means may comprise a second mating face configured to provide  
15 optical communication between said light transmission means and said first mating face when said speculum member is fitted to said probe head.

Preferably, the speculum member is disposable after use with one patient.

The speculum member preferably further comprises a plug removably fitted to said distal aperture, said plug configured to diffusedly reflect incident light  
20 thereon from said light transmission means in a known manner. The plug attachment to the speculum may be such that after shifting it into an inoperative position to be out of the optical path, it cannot be returned into the operative position, thus requiring replacement of the entire speculum by a new one.

The present invention thus provides an improved optical probe which  
25 enables qualitative measurements to be taken in parallel to enabling observation of the tissue. The probe improves the quality of transmission therethrough of the light reflected or refracted by the tissues. The probe is relatively simple in construction and simple to use, and is relatively inexpensive to manufacture.

Thus, according to another broad aspect of the present invention, there is  
30 provided an optical probe for transmitting light emanating from a target tissue along

at least two separate optical channels, comprising a probe head and a speculum member removably fitted to a distal end of said probe head, wherein:

said probe head comprises light transmission means for directing an illuminating light to said target tissue via a distal end of said speculum, and means  
5 for directing light emanating from said target tissue along at least two separate optical channels; and wherein

said speculum member is adapted for positioning said distal end thereof proximate to the target tissue.

According to yet another aspect of the invention, there is provided a  
10 measurement system for use in determining the patient's condition, the system comprising:

- (a) an optical measuring unit operable for carrying out spectral measurements, the measuring unit comprising a light source for generating light of predetermined spectrum, a detector for collecting light impinging thereon  
15 and generating data indicative thereof, said measuring unit comprising a plug that is shiftable between its operative and inoperative positions so as to be, respectively, in and out of the optical path of light propagating from the light source and having a highly diffusely reflective surface, the measuring unit being selectively operable to apply spectral measurements to said  
20 surface and obtain reference spectrum data indicative of the reflectance of incident light from said surface and to apply spectral measurements to the region of interest on patient's body to obtain measured spectral data indicative of the reflectance of the incident light from the region of interest;
- (b) a control unit for receiving and processing the measured data to generate  
25 output data indicative of the measurement results, the control unit comprising a memory utility for storing predetermined reference data representative of a value or a range of values for at least one predetermined measurable parameter corresponding to a healthy condition of a patient and for storing the reference spectrum; a data processing and analyzing utility  
30 preprogrammed for processing and analyzing the measured data by

- selecting a certain part of the measured data within at least one range of the predetermined light spectrum and normalizing said selected part of the measured data by the reference spectrum to thereby obtain a relative measured spectrum;
- 5       - applying a predetermined model to said relative measured spectrum to determine a corresponding value of said at least one predetermined measurable parameter for the measured patient and generate said output data indicative of association between the determined parameter value and the reference data.

10       According to yet another aspect of the invention, there is provided a method for processing spectral measured data to enable determination of a patient's condition, the method comprising processing spectral measured data indicative of reflection of predetermined incident light from a region of interest as a function of wavelengths of the incident light; said processing comprising selecting a  
15       predetermined part of the measured spectral data corresponding to at least one range of the predetermined incident light, normalizing the selected measured data to obtain a relative spectrum and applying a predetermined model to the relative spectrum to determine a corresponding value of at least one predetermined measurable parameter and generate output data indicative of association between  
20       the determined parameter value and preset reference data, said reference data being representative of a value or a range of values for said at least one predetermined measurable parameter corresponding to a healthy condition of a patient.

      According to yet another aspect of the invention, there is provided a method for use in determining a patient's condition, the method comprising:

- 25       (i) providing reference data representative of a value or a range of values for at least one predetermined measurable parameter corresponding to a healthy condition of a patient, and a certain reference spectrum corresponding to reflectance of a predetermined light spectrum from a reference highly reflective surface;

- (ii) applying spectral measurements to a region of interest on the patient's body with predetermined light spectrum and producing measured spectral data indicative thereof; and
- (iii) processing the measured data to generate output data indicative of the measurement results, said processing comprising selecting a part of the measured data within at least one range of the predetermined light spectrum and applying a predetermined model to the selected part of the measured data to determine a corresponding value of said at least one predetermined measurable parameter for the measured patient and generate said output data indicative of association between the determined parameter value and the reference data.

#### BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, preferred embodiments will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

**Fig. 1** is an isometric sectional side view of a first embodiment of the optical probe of the present invention;

**Fig. 2** is a cross-sectional side view of a second embodiment of the optical probe of the present invention;

**Fig. 3** shows in greater detail the distal end of the probe of Fig. 2;

**Fig. 4** schematically illustrates a measurement system according to the invention for use in determining the condition of a patient's ear;

**Fig. 5** illustrates a flow diagram of the main steps in the method according to the invention; and

**Figs. 6A-6D** exemplify how the method of the present invention can be used for determining the otitis media in the patient's ear.

## DETAILED DESCRIPTION OF THE INVENTION

The present invention in its one aspect relates to an optical probe for transmitting light emanating from a target tissue (constituting a region of interest) along at least two separate optical channels, comprising: a probe head and a speculum member removably fitted to a distal end of said probe head. The probe head comprises light transmission means for directing an illuminating light to said target tissue via a distal end of said speculum, and means for directing light emanating from said target tissue along at least two separate optical channels. The speculum member is adapted for positioning said distal end thereof proximate to the target tissue.

Unless otherwise stated, the term "proximal" (P) herein refers to a direction away from the target tissue and towards the user of the optical probe, while the term "distal" (D) refers to a direction towards the target tissue and away from the user.

Referring to Fig. 1, a first embodiment of the optical probe, generally designated by the numeral 100, comprises a speculum member 10 removably fitted to a probe head 50. The speculum member 10 is generally frustoconical in form, having a smaller distal end 11 with aperture 12, and a larger proximal end 15. The speculum member 10 is hollow, enabling optical communication between the aperture 12 and the proximal end 15.

The probe head 50 is also typically frustoconical in form, the smaller distal end 51 thereof generally configured for engagement with the speculum member 10. The inner conical surface of the proximal end 15 is typically configured to provide a press-fit engagement with the outer conical surface of the distal end 51 of the probe head. Alternatively, suitable engagement means such as a bayonet fitting or complementary screw threads may be provided for removably fitting the speculum member 10 to the probe head 50.

The probe head 50 is typically hollow, having a distal end 51 which is in optical communication with aperture 12 when the speculum member 10 is engaged with the probe head 50. The probe head 50 has an objective 80 at the proximal end thereof, which may be an eyepiece ocular, for example, to permit direct visual

observation of light passing through said aperture 12 along principal axis 99. Alternatively, the objective 80 may comprise any suitable video camera or CCD device, for recording images transmitted from a target tissue 300 via said aperture 12. The target tissue 300, which may be the ear canal, or vaginal walls, for example, according to the specific application of the probe, is illuminated by means of a  
5 suitable light source 20 via a suitable light transmission means such as a focusing element 22. Alternatively, the light source is remote from the probe 100, and a suitable optic fibre arrangement provides optical communication between the light source and the focusing element 22. Advantageously, the light source 20 and/or the  
10 focusing element 22 are aligned with the outer wall of the probe head 50, and thus at an angle with respect to the principal axis 99. Accordingly, the speculum member 10 is provided with an internal reflector 18 configured to direct illuminating light incident thereon from said focusing element 22 towards the aperture 12 and therefrom to the target tissue 300 when this is in close proximity to the probe 100.

15 As a result of illuminating the target tissue 300 with the illuminating light, light -typically reflected light- emanates from the tissue and passes into the interior of the probe 100 via the aperture 12. The probe head 50 comprises a beam splitter arrangement in the form of a parabolic mirror 60 having a central aperture 65. By means of this aperture 65, a first portion of light traveling from the distal aperture  
20 12 along the principal axis 99 is directed towards a first optical channel and objective 80, permitting visualization of the target tissue 300 either directly or indirectly. The parabolic mirror 60 has its axis of symmetry 92 inclined to the principal axis 99 and directed towards a convex mirror 66, positioned on the inner wall of the probe head, which in turn directs incident light thereon towards  
25 objective 68. Thus, a second portion of light traveling from the distal aperture 12 parallel to the principal axis 99 is reflected by the parabolic mirror 60 and convex mirror 66 and thus directed towards a second optical channel and objective 68. A suitable light sensor 69, or alternatively a suitable optical fibre arrangement, is provided at objective 68, and provides operative communication with a suitable

analysis unit (preferably a spectrometer), to enable analysis of the light received from the tissue sample.

Referring to Figs. 2 and 3, another embodiment of the optical probe, generally designated 200, is illustrated. The probe 200 comprises a speculum member 210 that releasably fits over the distal end 251 of the probe head 250.

As with the first embodiment, the speculum member 210 is generally frustoconical in form, having a smaller distal end 211 with aperture 212, and a larger proximal end 215. The speculum member 210 is hollow, enabling optical communication between the aperture 212 and the proximal end 215.

The probe head 250 is also typically frustoconical in form, the smaller distal end 251 thereof generally configured for engagement with the speculum member 210. The inner conical surface of the proximal end 215 is typically configured to provide a press-fit engagement with the outer conical surface of the distal end 251 of the probe head. Alternatively, suitable engagement means such as a bayonet fitting or complementary screw threads may be provided for removably fitting the speculum member 210 to the probe head 250.

The probe head 250 is typically hollow, having a distal end 251 in optical communication and close proximity with aperture 212. The probe head 250 has an objective 280 at the proximal end thereof, which may be an eyepiece ocular to permit direct visual observation of light passing through said aperture 212 along principal axis 299. Alternatively, the objective 280 may comprise any suitable video camera or CCD device, for recording images transmitted from a target tissue 300 via distal aperture 212. The target tissue 300, which may be the ear canal, or vaginal walls, for example, according to the specific application of the probe, is illuminated by means of a suitable light source 220 via a suitable light transmission means. In this embodiment the light transmission means comprises a waveguide arrangement in the form of a layer 240 of material having waveguiding properties, such as for example PMMA (polymethylmetacrylate) for example, and bonded or otherwise attached to the inner surface of the speculum member 210. The waveguiding layer 240 has a transmission face 231 proximate to the aperture 212, and a distal mating

face 232 in optical communication with the transmission face 231. Another waveguide 245 is provided in the probe head 250, and having a mating face 246 at one end thereof complementary to said mating face 232, and the other end of the waveguide 245 is connected to or connectable with the light source 220. The light source 220 may optionally be remote from the probe 200, and a suitable optic fibre arrangement provides optical communication between the light source and the wave guide 245. Thus, when the speculum member 210 is properly engaged with respect to the probe head 250, the mating faces 232 and 246 are aligned and in optical contact, enabling illumination light to be transmitted to the target tissue 300 via the transmission face 231, when the probe 200 is in close proximity to the tissue 300.

As with the first embodiment, as result of illuminating the target tissue 300 with the illuminating light, light -typically reflected light- emanates from the tissue and passes into the interior of the probe 200 via the aperture 212. The probe head 250 is typically hollow, enabling a first portion of light traveling from said aperture 212 along the principal axis 299 to be directed towards a first optical channel and towards objective 280, permitting visualization of the target tissue 300 either directly or indirectly. In this embodiment, the second optical channel comprises a suitable second waveguide for directing light from said aperture 211 towards a light sensor. The second waveguide is in the form of a layer of material 270 having waveguiding properties comprised on the outer distal surface of the probe head 250. The said second layer 270 is typically made from PMMA or the like, for example, and has a receiving face 271 proximate to the aperture 212, and a transmitting face 272 in optical communication with the receiving face 271 and adapted for enabling light from outside of aperture 212 to pass therethrough to said second transmitting face 272. The transmitting face 272 is adapted for optical communication with a suitable light sensor, directly or indirectly, or alternatively with a suitable optical fibre arrangement, which provides operative communication with a suitable analysis unit, typically a spectroscope, enabling analysis of the light received from the tissue sample. Preferably, the layer 270 is circumferentially covered by a

protective layer 277, made of for example metal or plastic, for minimizing damage to the waveguide, particularly during engagement and disengagement of the speculum member 210.

Preferably, the probe 200, and at least the probe head 250, is accommodated  
5 in a suitable housing 295, which also comprises a handle 296 to facilitate handling of the probe by the user.

In all embodiments, the speculum member is preferably disposable after one or multiple use with one patient, and is thus preferably made from a relatively inexpensive material.

10 Preferably, but optionally, and in all embodiments, the speculum member comprises a plug (which is not specifically shown) that closes the distal aperture thereof. The plug is mounted so as to be shiftable from its operative position when it closes the aperture and thus is in the optical path of light propagating through the probe when in operation, and an inoperative position when it is out of said optical  
15 path. The plug at least at its inner surface is made from a suitable material that diffuses and reflects incident light thereon, and thus may be used by the optical probe of the present invention for calibration purposes. Thus, prior to using the optical probe with a patient, the intensity of diffused reflected light obtained via the second channel when the plug is internally illuminated by the illuminating light  
20 may be compared to the intensity of the illumination light. The ratio of intensities thus obtained is the compared with expected nominal datum values, and any deviation therefrom may then be applied to any qualitative measurements of intensities taken of the target tissues, the plug having being removed before such measurements.

25 In another aspect, the present invention relates to a measurement system and method for use in determining the patient's condition, in particular the ear condition. More specifically the system is used for determining whether the ear is healthy or is infected with otitis media or serous otitis media, and is therefore described below with respect to this specific application.

Referring to Fig. 4, a measurement system, generally at 400 is schematically illustrated. The system 400 is configured for determining the condition of a patient's ear. The system 400 comprises such main constructional parts as a measuring unit 402 for applying spectral measurements to the inside of the patient's ear; and a control unit 404 connectable to the measuring unit either via a communication cable or wireless communication means.

The measuring unit 402 is an optical probe, which may be designed as described above with reference to Figs. 1-3. Generally, the measuring unit 402 includes a light source assembly 406 for producing illuminating radiation of a predetermined wavelength range, for example 400-1100nm; a spectrometric detector assembly 408 for receiving light response of the illuminated region in the ear (light reflected from the illuminated region) and generating measured data indicative thereof. The measuring unit preferably also comprises means for spatially separating incident and reflected light. These may for example be optical fibers, and/or mirrors' arrangement.

The control unit 404 is typically a computer system including *inter alia* a memory utility 410 for storing certain reference data; a data processing and analyzing utility 412; and a user interface utility 414. The data processing and analyzing utility is preprogrammed for processing the received measured data by applying thereto a predetermined mathematical model to obtain the processing results in the form of at least spectral factor, and for analyzing the spectral factor in accordance with the reference data to determine whether the spectral factor satisfies a predetermined condition. The spectral factor is a measurable value determined from the spectral response of a region of interest in the patient's body, as will be described further below.

The reference data is obtained by performing a general learning mode, and carrying out a calibration stage prior to applying a measurement session to a specific patient. The learning mode consists of applying numerous measurements to various patients and determining, per each disease to be detected, a value or a range of values for at least one spectral factor defining a boundary between the healthy

and diseased condition. The spectral factor is determined by processing measured spectral data in the form of relative spectrum of the region of interest (relative light intensity as a function of wavelength) with the predetermined mathematical model, as will be described below.

5       The main steps in the method of the present invention will now be described with reference to **Fig. 5** and examples of **Figs. 6A-6C**.

Initially, a calibration stage is carried out - Step I. Generally, the calibration stage is aimed at eliminating or at least significantly reducing the effects of variation in the light source and detector response in the measured data. Such variations exist between different instruments, and different times, even on the same instrument. At the calibration stage, a white reference spectrum,  $R_w(\lambda)$ , is obtained. This can be implemented as described above, namely, by placing a highly reflective (preferably, diffusive reflective) element at the distal end of the measuring unit (in the case of otoscope, the distal end of a speculum) and operating the measuring unit to determine the reflectivity of this white surface, which is considered to be equal to the intensity of incident light reaching the region of interest.

Then, an actual measurement session (at least one measurement) is applied to the region of interest (e.g., patient's ear) - Step II. The region of interest is illuminated with predetermined incident radiation, reflected light is detected, and measured spectral data is produced in the form of the detected light intensity as a function of wavelength of the incident light.

**Figs. 6A and 6B** exemplify, respectively, the ear spectrum (measured spectral data) and white spectrum (reference spectral data). In the specific, but non-limiting, example of determining the patient's ear condition, incident light of 300-1400nm is used. The white spectrum is obtained prior to applying the actual measurement session to each patient and is stored in the memory utility. It should be noted that generally the calibration stage may be conducted periodically and not necessarily repeated for each new patient.

The measured data is received at the control unit where it is processed and analyzed with the predetermined mathematical model – step III. The processing of the measured data consists of normalizing it by the reference spectrum to obtain a normalized reflectivity spectrum  $R(\lambda)$ . The normalized reflectivity spectrum is then  
 5 processed to determine a corresponding value of at least one measurable parameter (the so-called “spectral factor”). The normalized reflectivity spectrum  $R(\lambda)$  is independent of instrument number  $j$  and of time  $t$ .

Mathematically, the normalization process can be described as follows:

$$E_j(\lambda, t) = A I_j(\lambda, t) R_E(\lambda) D_j(\lambda, t)$$

$$W_j(\lambda, t) = B I_j(\lambda, t) R_W(\lambda) D_j(\lambda, t)$$

wherein:

$E_j(\lambda, t)$  is the measured spectrum of the region of interest (e.g., ear);

$W_j(\lambda, t)$  is the measured white reference spectrum;

$j$  is the instrument number;

$t$  is the time;

$\lambda$  is the wavelength of incident light;

$A, B$  are unknown amplitudes;

$I_j(\lambda, t)$  is the illumination spectrum of light source for instrument  $j$ ;

$D_j(\lambda, t)$  is the response spectrum of the detector for instrument  $j$ ;

$R_E(\lambda)$  is the reflectivity spectrum of the ear drum;

$R_W(\lambda)$  is the reflectivity of a standard white surface

The normalized reflectivity spectrum is determined as:

$$R(\lambda) = E_j(\lambda, t) / W_j(\lambda, t) = C R_E(\lambda) / R_W(\lambda)$$

Here, parameter  $C$  is an unknown amplitude, which depends *inter alia* upon  
 25 the signal integration time and the distance of the instrument from the patient's ear drum. To eliminate the effect of parameter  $C$ , the normalized reflectivity spectrum is further normalized by a certain wavelength  $\lambda_0$  from the incident light spectrum. In the present example, this is implemented by setting a relative spectrum:  $r(\lambda) = R(\lambda) / R(\lambda_0)$ , so that  $r(\lambda_0) = 1$ , wherein  $\lambda_0$  is chosen in the center of the wavelength

range of incident light (e.g., visible spectrum), and  $r(\lambda)$  is a "relative" spectrum, insofar as all intensities are measured relative to the intensity at  $\lambda_0$ .

An example of the relative spectrum of a sample is shown in Fig. 6C. In this specific example of determining the patient's ear condition for the purposes of detecting the existence of serous otitis media (SOM) and acute otitis media (AOM), the normalized spectrum for 400-1000nm is determined. The value of  $\lambda_0$  is chosen in the center of this range, namely to be about 700nm.

The inventors have found that a specific disease is characterized by at least one predetermined spectral range, from the entire measured spectrum, where the spectral behavior of the light response is maximally affected by the disease. For example, in order to detect the existence of serous otitis media (SOM) and acute otitis media (AOM), the spectral ranges of interest are 500-650nm (visible range) and 800-950nm (IR range).

The processing of the relative spectrum  $r(\lambda)$  generally consists of applying the predetermined model to either the entire normalized spectrum or at least one selected region of this spectrum (region characterized by the maximal effects of a specific disease). In this specific example, the mathematical model utilizes a Likelihood Algorithm, and the processing consists of the following:

The relative spectrum  $r(\lambda)$  is sampled at certain discrete wavelengths, to generate a feature vector,  $\underline{r}$ :

$$\underline{r} = \{ r(\lambda_n), n = 1, 2 \dots N \}$$

Two populations are considered: (A) healthy ears and (B) infected ears. By doing clinical tests on a large sample of ears of both types, the probability densities  $f(\underline{r} | A)$  and  $f(\underline{r} | B)$  are learned. For example, using Gaussian probability densities,

$$f(\underline{r} | A) = g(\underline{r}, \underline{\mu}_A, P_A)$$

$$f(\underline{r} | B) = g(\underline{r}, \underline{\mu}_B, P_B)$$

wherein

$$g(\underline{r}, \underline{\mu}, P) = [2\pi \det(P)]^{-N/2} \exp \left[ -1/2 (\underline{r} - \underline{\mu})^T P^{-1} (\underline{r} - \underline{\mu}) \right]$$

$$\underline{\mu} = \text{mean}(\underline{r})$$

$P = \text{covariance}(\mathbf{r}) = N \times N$  matrix

A new patient arrives, and his ear spectrum is measured. His feature vector is denoted by  $\underline{x}$ . In order to diagnose the ear as healthy or infected, the algorithm forms the log-likelihood ratio:

$$\begin{aligned} L1(\underline{x}) &= 2 \log \{ f(\underline{x} | B) / f(\underline{x} | A) \} \\ &= (\underline{x} - \underline{\mu}_A)^T P_A^{-1} (\underline{x} - \underline{\mu}_A) - (\underline{x} - \underline{\mu}_B)^T P_B^{-1} (\underline{x} - \underline{\mu}_B) \end{aligned}$$

Then:

If  $L1(\underline{x}) \leq T1$ , diagnosis = A (healthy)

If  $L1(\underline{x}) > T1$ , diagnosis = B (infected)

The numerical value of the threshold  $T1$  is chosen to achieve a desired level of sensitivity (i.e., the probability of correctly diagnosing an infected ear).

Considering next the subdivision of infected ears into 2 classes: ( $B_1$ ) serous otitis media (SOM) and ( $B_2$ ) acute otitis media (AOM), if  $\underline{x}$  is diagnosed as infected ( $L1(\underline{x}) > T1$ ), a second log-likelihood ratio is formed:

$$\begin{aligned} L2(\underline{x}) &= 2 \log \{ f(\underline{x} | B_2) / f(\underline{x} | B_1) \} \\ &= (\underline{x} - \underline{\mu}_{B1})^T P_{B1}^{-1} (\underline{x} - \underline{\mu}_{B1}) - (\underline{x} - \underline{\mu}_{B2})^T P_{B2}^{-1} (\underline{x} - \underline{\mu}_{B2}) \end{aligned}$$

and diagnosis is made as follows:

If  $L2(\underline{x}) \leq T2$ , diagnosis =  $B_1$  (SOM)

If  $L2(\underline{x}) > T2$ , diagnosis =  $B_2$  (AOM)

wherein, again,  $T2$  is a threshold which is chosen to achieve a desired level of sensitivity (i.e., the probability of correctly diagnosing AOM).

Fig. 6D shows the values of the measurable parameters  $L1$  and  $L2$  for normal (NOR), SOM and AOM conditions in the two-dimensional likelihood space, as obtained for the specific example of Figs. 6A-6C.

The values  $L1$  and  $L2$  (log-likelihood) actually present the spectral factors being in the well-defined association with the value or range of values corresponding to the healthy condition of the ear and can thus be used by the physician for decision making. Preferably, these values  $L1$  and  $L2$  are further scaled to produce "spectral factors" that may be of better diagnostic value to a physician.

They are continuous numbers that, over time and experience, may have value for borderline cases, much in the way that blood counts and iron levels in the blood are measured in continuous fashion. The following is the example of such scaling:

$$S1(x) = a1 + b1 * (L1(x) - T1)$$

5  $S2(x) = a2 + b2 * (L2(x) - T2)$

Here, coefficients a1, a2, b1 and b2 (that need not be necessarily different from each other) are appropriately selected to provide a scale which can be easily remembered by the physician, and thus facilitating the decision making.

10 The technique of the present invention thus provides for automatically determining the patient's condition by obtaining and analyzing the spectral response of the region of interest in the patient's body, and provides for effective collection of this spectral response. Output data presented to a physician (displayed on the monitor of the control unit) thus includes just the calculated spectral factor and preferably also the value or range of values for the spectral factor at normal (non-  
15 diseased) condition.

Those skilled in the art will readily appreciate that various modifications and changes can be applied to the embodiments of the invention as hereinbefore described without departing from its scope defined in and by the appended claims.

**CLAIMS:**

1. A measurement system for use in determining a patient's condition, the system comprising:

- 5 (a) an optical measuring unit operable for applying spectral measurements to the region of interest in a patient's body with predetermined light spectrum and producing measured spectral data indicative thereof; and
- 10 (b) a control unit for receiving and processing the measured data to generate output data indicative of the measurement results, the control unit comprising a memory utility for storing predetermined reference data representative of a value or a range of values for at least one predetermined measurable parameter corresponding to a healthy condition of a patient; a data processing and analyzing utility preprogrammed for processing and analyzing the measured data by selecting a certain part of the measured data within at least one range of the predetermined light spectrum and applying a
- 15 predetermined model to the selected part of the measured data to determine a corresponding value of said at least one predetermined measurable parameter for the measured patient and to generate said output data indicative of association between the determined parameter value and the reference data.
- 20 2. The system of Claim 1, wherein the measuring unit is configured for determining a reference spectrum indicative of the light intensity illuminating the region of interest as a function of wavelengths of said predetermined incident light.
3. The system of Claim 2, wherein the processing of the measured spectral data comprises normalizing the measured spectral data by said reference spectrum,
- 25 thereby obtaining a normalized reflectivity spectrum which then undergoes said processing by the predetermined model.
4. The system of Claim 3, wherein the processing and analyzing of the measured data comprises optimizing the normalized reflectivity spectrum by further normalizing it by a certain wavelength  $\lambda_0$  within said selected spectrum range, such

that all the light intensities are measured relative to the intensity at wavelength  $\lambda_0$ , thereby obtaining a relative spectrum that undergoes said processing with the predetermined model.

- 5 5. The system of Claim 1, wherein said at least one selected range of the predetermined light spectrum is defined by the patient's condition to be detected.
6. The system of Claim 1, for use in determining the existence of otitis media condition in the patient's ear, the predetermined light spectrum being within 300-1400nm.
7. The system of Claim 6, wherein the selected range of the predetermined light  
10 spectrum includes a range of 500-650nm.
8. The system of Claim 6, wherein the selected range of the predetermined light spectrum includes a range of 800-950nm.
9. The system of Claim 7, wherein the selected range of the predetermined light spectrum includes a range of 800-950nm.
- 15 10. The system of Claim 4, wherein said processing with the predetermined model comprises applying a Likelihood Algorithm to the relative spectrum, calculating a feature vector as a function of wavelengths within said selected range, and calculating a log-likelihood ratio between the feature vector of the relative spectrum and that of the reference data, said ratio presenting said at least one measurable  
20 parameters indicative of the patient's condition.
11. The system of Claim 4, wherein said processing with the predetermined model comprises applying a Likelihood Algorithm to the relative spectrum, calculating a feature vector as a function of wavelengths within said selected range, and calculating a log-likelihood ratio between the feature vector of the relative spectrum  
25 and that of the reference data, said ratio being scalable to determine said at least measurable parameter indicative of the patient's condition.
12. The system of Claim 1, wherein said control unit is configured as an expert system capable of timely analyzing the calculated measurable parameters and optimizing the model accordingly.

13. The system of Claim 6, wherein the measuring unit is configured for determining a reference spectrum indicative of the light intensity illuminating the region of interest as a function of wavelengths of said predetermined incident light.

14. The system of Claim 13, wherein the processing of the measured spectral data  
5 comprises normalizing the measured spectral data by said reference spectrum, thereby obtaining a normalized reflectivity spectrum which then undergoes said processing by the predetermined model.

15. The system of Claim 14, wherein the processing and analyzing of the measured data comprises optimizing the normalized reflectivity spectrum by further  
10 normalizing it by a certain wavelength  $\lambda_0$  within said selected spectrum range, such that all the light intensities are measured relative to the intensity at wavelength  $\lambda_0$ , thereby obtaining a relative spectrum that undergoes said processing with the predetermined model.

16. The system of Claim 15, wherein said processing with the predetermined model  
15 comprises applying to a Likelihood Algorithm to the relative spectrum, calculating a feature vector as a function of wavelengths within said selected range, and calculating a log-likelihood ratio between the feature vector of the relative spectrum and that of the reference data.

17. The system of Claim 15, wherein said processing with the predetermined model  
20 comprises applying a Likelihood Algorithm to the relative spectrum, calculating a feature vector as a function of wavelengths within said selected range, and calculating a log-likelihood ratio between the feature vector of the relative spectrum and that of the reference data, said ratio being scalable to determine said at least measurable parameter indicative of the patient's condition

25 18. The system of Claim 16, wherein said processing of the relative spectrum comprises determining two measurable parameters indicative of the existence in the patient's ear of, respectively, serous otitis media (SOM) and acute otitis media (AOM).

19. The system of Claim 14, wherein said normalizing of the measured spectral data by said reference spectrum comprises presenting the measured spectrum  $E_j(\lambda, t)$  and the reference spectrum  $W_j(\lambda, t)$  as, respectively,

$$E_j(\lambda, t) = A I_j(\lambda, t) R_E(\lambda) D_j(\lambda, t) \text{ and } W_j(\lambda, t) = B I_j(\lambda, t) R_W(\lambda) D_j(\lambda, t)$$

5 wherein  $j$  is the number of the measuring unit,  $t$  is the time,  $\lambda$  is the wavelength of incident light,  $A$  and  $B$  are unknown amplitudes,  $I_j(\lambda, t)$  is the illumination spectrum of light source for the measuring unit  $j$ ;  $D_j(\lambda, t)$  is the light response spectrum of a detector assembly of for measuring unit  $j$ ;  $R_E(\lambda)$  is the reflectivity spectrum of the region of interest; and  $R_W(\lambda)$  is the reflectivity of a reference surface used in obtaining said reference  
10 spectrum, the normalized reflectivity spectrum being thus determined as:

$$R(\lambda) = E_j(\lambda, t) / W_j(\lambda, t) = C R_E(\lambda) / R_W(\lambda),$$

wherein parameter  $C$  is a light signal amplitude depending *inter alia* upon a signal integration time and a distance between the measuring unit and the region of interest.

20. The system of Claim 19, wherein the processing and analyzing of the measured  
15 relative spectrum comprises optimizing the normalized reflectivity spectrum by further normalizing it by a certain wavelength  $\lambda_0$  within said selected spectrum range, such that all the light intensities are measured relative to the intensity at wavelength  $\lambda_0$ , thereby obtaining a relative spectrum in which the effect of parameter  $C$  is eliminated, said processing with the predetermined model being  
20 applied to the relative spectrum.

21. The system of Claim 20, wherein said further normalizing comprises setting the relative spectrum  $r(\lambda) = R(\lambda) / R(\lambda_0)$  so that  $r(\lambda_0) = 1$ .

22. The system of Claim 20, wherein the selected value of  $\lambda_0$  is the center of the wavelength range of said predetermined incident light.

25 23. The system of Claim 22, wherein the creation of the reference data and the model comprises:

- sampling a spectrum  $r(\lambda)$  at certain discrete wavelengths, to generate a feature vector  $\underline{r} = \{ r(\lambda_n), n = 1, 2 \dots N \}$ ;

- learning probability densities  $f(\underline{r} | A)$  and  $f(\underline{r} | B)$  for populations including (A) healthy ears and (B) infected ears; and

- defining said value or range of values as a threshold T1 chosen to achieve a desired level of sensitivity corresponding to the probability of correctly diagnosing the existence of the predetermined condition of the patient's ear.

24. The system of Claim 23, wherein the probability densities include Gaussian probability densities  $f(\underline{r} | A) = g(\underline{r}, \underline{\mu}_A, P_A)$  and  $f(\underline{r} | B) = g(\underline{r}, \underline{\mu}_B, P_B)$ , wherein  $g(\underline{r}, \underline{\mu}, P) = [2\pi \det(P)]^{-N/2} \exp[-1/2 (\underline{r} - \underline{\mu})^T P^{-1} (\underline{r} - \underline{\mu})]$ ,  $\underline{\mu} = \text{mean}(\underline{r})$ ,  $P = \text{covariance}(\underline{r}) = N \times N$  matrix.

25. The system of Claim 24, wherein the processing and analyzing of the relative spectrum comprises processing the measured feature vector to determine said at least one measurable parameters L1 as the log-likelihood ratio:

$$L1(\underline{x}) = 2 \log \{ f(\underline{x} | B) / f(\underline{x} | A) \} \\ = (\underline{x} - \underline{\mu}_A)^T P_A^{-1} (\underline{x} - \underline{\mu}_A) - (\underline{x} - \underline{\mu}_B)^T P_B^{-1} (\underline{x} - \underline{\mu}_B)$$

26. The system of Claim 25, wherein the processing and analyzing of the relative spectrum comprises determining the association between said ratio and the predetermined threshold value T1 indicative of the existence of the otitis media in the patient's ear.

27. The system of Claim 26, wherein said processing and analyzing provides for identifying wherein the otitis media includes serous otitis media (SOM) or acute otitis media (AOM).

28. The system of Claim 27, wherein the creation of said reference data and said model comprises defining said value or range of values as a threshold T2 chosen to achieve a desired level of sensitivity corresponding to the probability of correctly diagnosing the existence of the serous otitis media (SOM) and acute otitis media (AOM).

29. The system of Claim 28, wherein said processing and analyzing comprises:

- processing the measured feature vector to determine another measurable parameter L2 as the log-likelihood ratio:

$$L2(\underline{x}) = 2 \log \{ f(\underline{x} | B_2) / f(\underline{x} | B_1) \}$$

$$= (\underline{X} - \underline{\mu}_{B1})^T P_{B1}^{-1} (\underline{X} - \underline{\mu}_{B1}) - (\underline{X} - \underline{\mu}_{B2})^T P_{B2}^{-1} (\underline{X} - \underline{\mu}_{B2})$$

- determining the association between said ratio L2 and the predetermined threshold value T2 indicative of whether the detected otitis media is SOM or AOM.

5 30. The system of Claim 1, wherein said measuring unit is configured as an optical probe for transmitting light emanating from a target tissue in the region of interest along at least two separate optical channels, the probe comprising a probe head and a speculum member removably fitted to a distal end of said probe head, wherein said probe head comprises light transmission means for directing an illuminating light to said target tissue via a distal end of said speculum, and means for directing  
10 light emanating from said target tissue along at least two separate optical channels; and wherein said speculum member is adapted for positioning said distal end thereof proximate to the target tissue.

31. The system of Claim 30, wherein said distal end of said speculum member comprises an optical aperture for enabling illuminating light and emanating light to  
15 pass therethrough from and to said optical probe.

32. The system of Claim 31, wherein said at least two separate optical channels comprise:

a first channel for enabling qualitative analysis of said light emanating from said target tissue; and

20 a second channel for enabling quantitative analysis of said light emanating from said target tissue.

33. The system of Claim 32, wherein said speculum member comprises an internal reflecting mirror for directing illuminating light from said light transmission means to said distal end.

25 34. The system of Claim 33, wherein said probe head comprises a beam splitter arrangement for splitting light traveling in a proximal direction from said distal end into said first channel and said second channel.

35. The system of Claim 34, wherein said beam splitter arrangement comprises a parabolic mirror having an aperture therein.

36. The system of Claim 35, wherein said aperture is configured for directing a first portion of said light traveling from said distal end therethrough along said first channel and towards an objective.

37. The system of Claim 36, wherein said objective comprises an eyepiece ocular.

5 38. The probe of Claim 36, wherein said objective comprises a suitable camera means for recording said image.

39. The system of Claim 35, wherein said parabolic mirror comprises an optical focusing element for directing a second portion of said light traveling from said distal end along said second channel and towards a light sensor.

10 40. The system of Claim 32, wherein said speculum member comprises a suitable first waveguide for directing illuminating light from said light transmission means to said distal end.

41. The system of Claim 40, wherein said first waveguide is in the form of a first layer of material having waveguiding properties comprised in said speculum member, said first layer having a transmitting face proximate to said distal end, and  
15 a first mating face in optical communication with said transmitting face and adapted for enabling illumination light from said light transmission means to pass therethrough to said transmitting face when said speculum member is fitted to said probe head.

20 42. The system of Claim 41, wherein said light transmission means comprises a second mating face configured to provide optical communication between said light transmission means and said first mating face when said speculum member is fitted to said probe head.

43. The system of Claim 41, wherein said first channel is in the form of a proximal aperture comprised in said probe head, said aperture being configured for directing  
25 a first portion of said light traveling from said distal end therethrough and towards an objective.

44. The system of Claim 42, wherein said first channel is in the form of a proximal aperture comprised in said probe head, said aperture being configured for directing

a first portion of said light traveling from said distal end therethrough and towards an objective.

**45.** The system of Claim 44, wherein said objective comprises an eyepiece ocular.

**46.** The system of Claim 44, wherein said objective comprises a suitable camera

5 means for recording said image.

**47.** The system of Claims 41, wherein said first layer is made from PMMA.

**48.** The system of Claims 40, wherein said second channel comprises a suitable second waveguide for directing light from said distal end towards a light sensor.

10 **49.** The system of Claims 40, wherein said second waveguide is in the form of a second layer of material having waveguiding properties comprised in said probe head, said second layer having a second receiving face proximate to said distal end, and a second transmitting face in optical communication with said second receiving face and adapted for enabling light from outside of said distal end to pass therethrough from said second receiving face to said second transmitting face.

15 **50.** The system of Claim 49, wherein said second transmitting face is in optical communication with a suitable light sensor.

**51.** The system of Claim 49, wherein said second layer is made from PMMA.

**52.** The system of Claim 50, wherein said second layer is made from PMMA.

20 **53.** The system of Claim 49, wherein said light sensor is operatively connected to a suitable spectrometer.

**54.** The system of Claim 51, wherein said light sensor is operatively connected to a suitable spectrometer.

**55.** The system of Claim 52, wherein said light sensor is operatively connected to a suitable spectrometer.

25 **56.** The system of Claim 30, wherein said speculum member is disposable after use with one patient.

**57.** The system of Claim 30, wherein said speculum member is adapted for positioning said distal end thereof within an ear canal of a patient proximate to the ear drum thereof.

58. The system of Claim 30, wherein said speculum member is adapted for positioning said distal end thereof within a the vaginal canal of a patient proximate to the ear drum thereof.

59. The system of Claim 30, wherein said speculum member further comprises  
5 a plug removably fitted to said distal aperture, said plug configured to diffusely reflect incident light thereon from said light transmission means in a known manner.

60. An optical probe for transmitting light emanating from a target tissue along at least two separate optical channels, comprising a probe head and a speculum  
10 member removably fitted to a distal end of said probe head, wherein:

said probe head comprises light transmission means for directing an illuminating light to said target tissue via a distal end of said speculum, and means for directing light emanating from said target tissue along at least two separate optical channels; and wherein

15 said speculum member is adapted for positioning said distal end thereof proximate to the target tissue.

61. A control unit configured for receiving spectral measured data from a region of interest on a patient's body, and processing the received data to generate output data indicative of the patient's condition, the control unit comprising a memory utility  
20 for storing predetermined reference data representative of a value or a range of values for at least one predetermined measurable parameter corresponding to a healthy condition of a patient and for storing the reference spectrum; a data processing and analyzing utility preprogrammed for processing and analyzing the measured data by:

- 25 - obtaining a relative spectral, said obtaining including selecting a part of the measured data within at least one range of the predetermined light spectrum and normalizing said selected part of the measured data by the reference spectrum;
- 30 - applying a predetermined model to the relative spectrum to determine a corresponding value of said at least one predetermined measurable

parameter for the measured patient and generate said output data indicative of association between the determined parameter value and the reference data.

62. A measurement system for use in determining the patient's condition, the system comprising:

- (a) an optical measuring unit operable for carrying out spectral measurements, the measuring unit comprising a light source for generating light of predetermined spectrum, a detector for collecting light impinging thereon and generating data indicative thereof, said measuring unit comprising a plug that is shiftable between its operative and inoperative positions so as to be, respectively, in and out of the optical path of light propagating from the light source and having a highly diffusely reflective surface, the measuring unit being selectively operable to apply spectral measurements to said surface and obtain reference spectrum data indicative of the reflectance of incident light from said surface and to apply spectral measurements to the region of interest on patient's body to obtain measured spectral data indicative of the reflectance of the incident light from the region of interest;
- (b) a control unit for receiving and processing the measured data to generate output data indicative of the measurement results, the control unit comprising a memory utility for storing predetermined reference data representative of a value or a range of values for at least one predetermined measurable parameter corresponding to a healthy condition of a patient and for storing the reference spectrum; a data processing and analyzing utility preprogrammed for processing and analyzing the measured data by
  - obtaining a relative spectral, said obtaining including selecting a part of the measured data within at least one range of the predetermined light spectrum and normalizing said selected part of the measured data by the reference spectrum;
  - applying a predetermined model to the relative spectrum to determine a corresponding value of said at least one predetermined measurable

parameter for the measured patient and generate said output data indicative of association between the determined parameter value and the reference data.

5 63. A program storage device readable by machine, tangibly embodying a program of instructions executable by the machine to perform method steps for receiving spectral data measured from a region of interest on a patient's body, and processing the received data to generate output data indicative of the patient's condition, the storage device comprising a memory utility for storing predetermined reference data representative of a value or a range of values for at least one predetermined  
10 measurable parameter corresponding to a healthy condition of a patient and for storing the reference spectrum; a data processing and analyzing utility preprogrammed for processing and analyzing the measured data by obtaining a relative spectral, said obtaining including selecting a part of the measured data within at least one range of the predetermined light spectrum and normalizing said  
15 selected part of the measured data by the reference spectrum; applying a predetermined model to the relative spectrum to determine a corresponding value of said at least one predetermined measurable parameter for the measured patient and generate said output data indicative of association between the determined parameter value and the reference data.

20 64. A computer program product comprising a computer useable medium having computer readable program code embodied therein for processing spectral data measured from a region of interest on a patient's body, the computer program product comprising: a data processing and analyzing utility for selecting a part of the measured data within at least one predetermined range of a light spectrum used  
25 in the measured data and utilizing a reference spectrum to normalize said selected part of the measured data to obtain a relative spectrum, applying a predetermined model to the relative spectrum and utilizing reference data representative of a value or a range of values for at least one predetermined measurable parameter corresponding to a healthy condition of a patient, to thereby determine a value of  
30 said at least one predetermined measurable parameter corresponding to the

measured data and generate output data indicative of association between the determined parameter value and the reference data.

65. A method for processing spectral measured data to enable determination of a patient's condition, the method comprising processing the spectral measured data indicative of reflection of predetermined incident light from a region of interest as a function of wavelengths of the incident light; said processing comprising selecting a predetermined part of the measured spectral data corresponding to at least one range of the predetermined incident light, normalizing the selected measured data to obtain a relative spectrum, and applying a predetermined model to the relative spectrum to determine a corresponding value of at least one predetermined measurable parameter and to generate output data indicative of association between the determined parameter value and preset reference data, said reference data being representative of a value or a range of values for said at least one predetermined measurable parameter corresponding to a healthy condition of a patient.

66. A method for use in determining a patient's condition, the method comprising:

- (i) providing reference data representative of a value or a range of values for at least one predetermined measurable parameter corresponding to a healthy condition of a patient, and a certain reference spectrum corresponding to reflectance of a predetermined light spectrum from a reference highly reflective surface;
- (ii) applying spectral measurements to a region of interest on the patient's body with predetermined light spectrum and producing measured spectral data indicative thereof; and
- (iii) processing the measured data to generate output data indicative of the measurement results, said processing comprising selecting a part of the measured data within at least one range of the predetermined light spectrum and applying a predetermined model to the selected part of the measured data to determine a corresponding value of said at least one predetermined measurable parameter for the measured patient and generate said output data

— 34 —

indicative of association between the determined parameter value and the reference data.

### ABSTRACT

A measurement system and method are presented for use in determining a patient's condition. The system comprises an optical measuring unit and a control unit connectable to the output of the measuring unit. The optical measuring unit is  
5 configured and operable for applying spectral measurements to the region of interest in a patient's body with predetermined light spectrum and producing measured spectral data indicative thereof. The control unit is operable for receiving and processing the measured data to generate output data indicative of the measurement results. The control unit comprises a memory utility for storing  
10 predetermined reference data representative of a value or a range of values for at least one predetermined measurable parameter corresponding to a healthy condition of a patient; a data processing and analyzing utility preprogrammed for processing and analyzing the measured data by selecting a part of the measured data within at least one range of the predetermined light spectrum and applying a predetermined  
15 model to the selected part of the measured data to determine a corresponding value of said at least one predetermined measurable parameter and generate said output data indicative of association between the determined parameter value and the reference data.

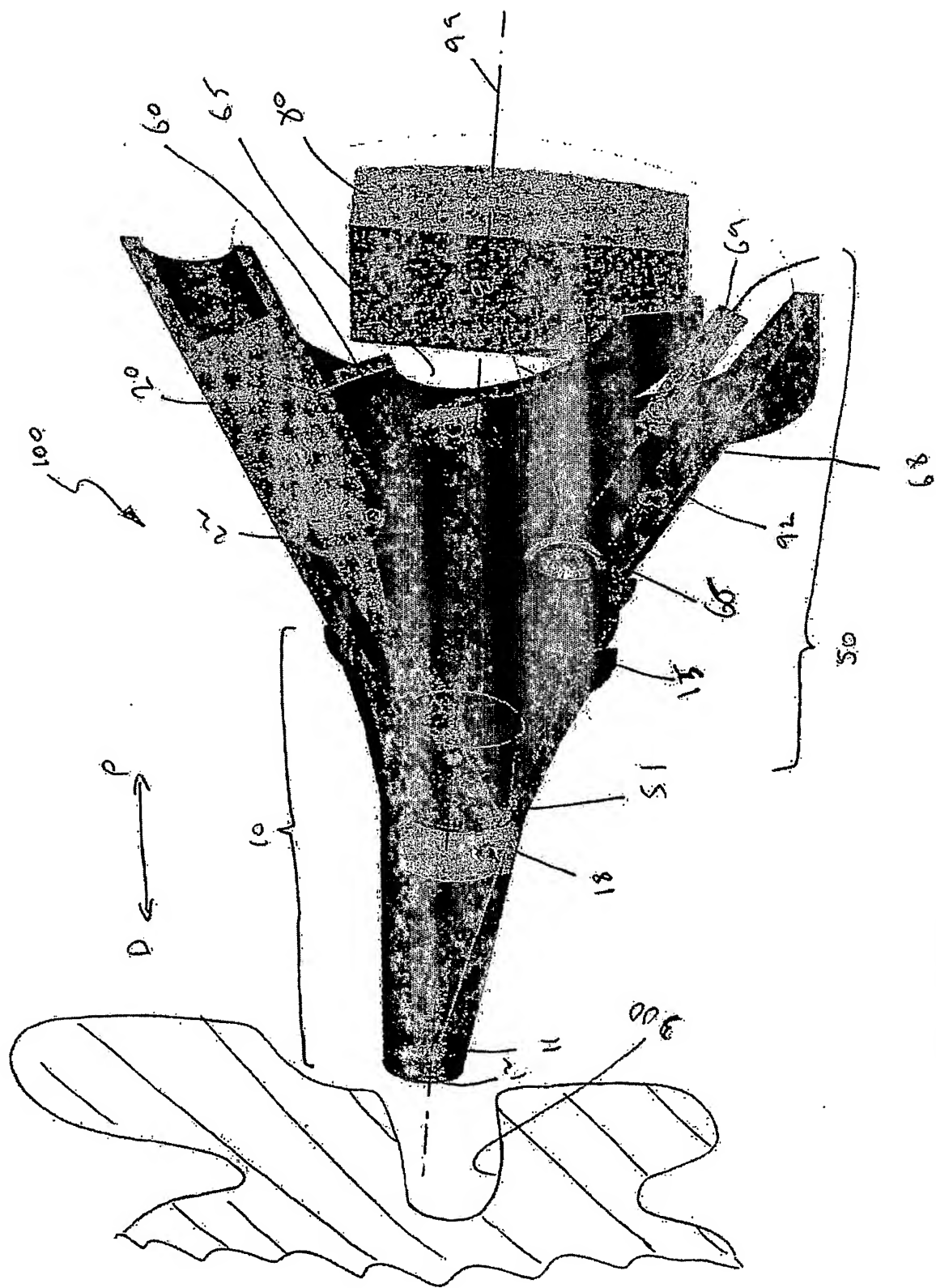


FIGURE 1

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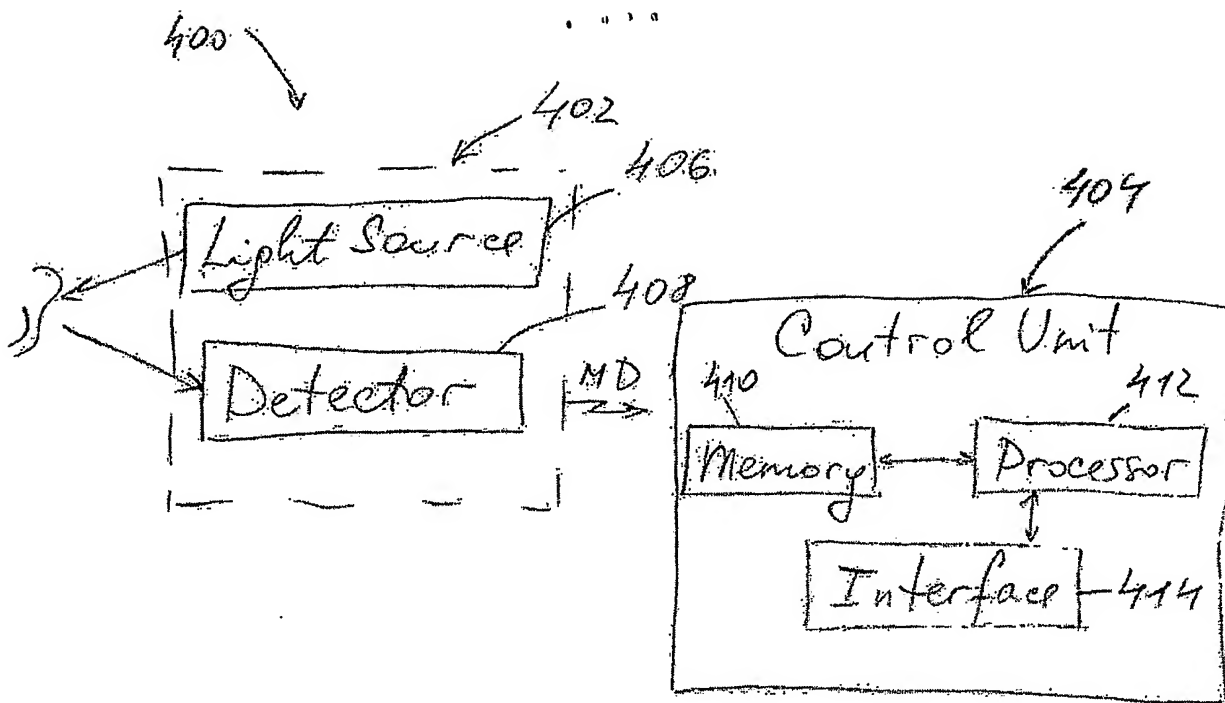


Fig. 4

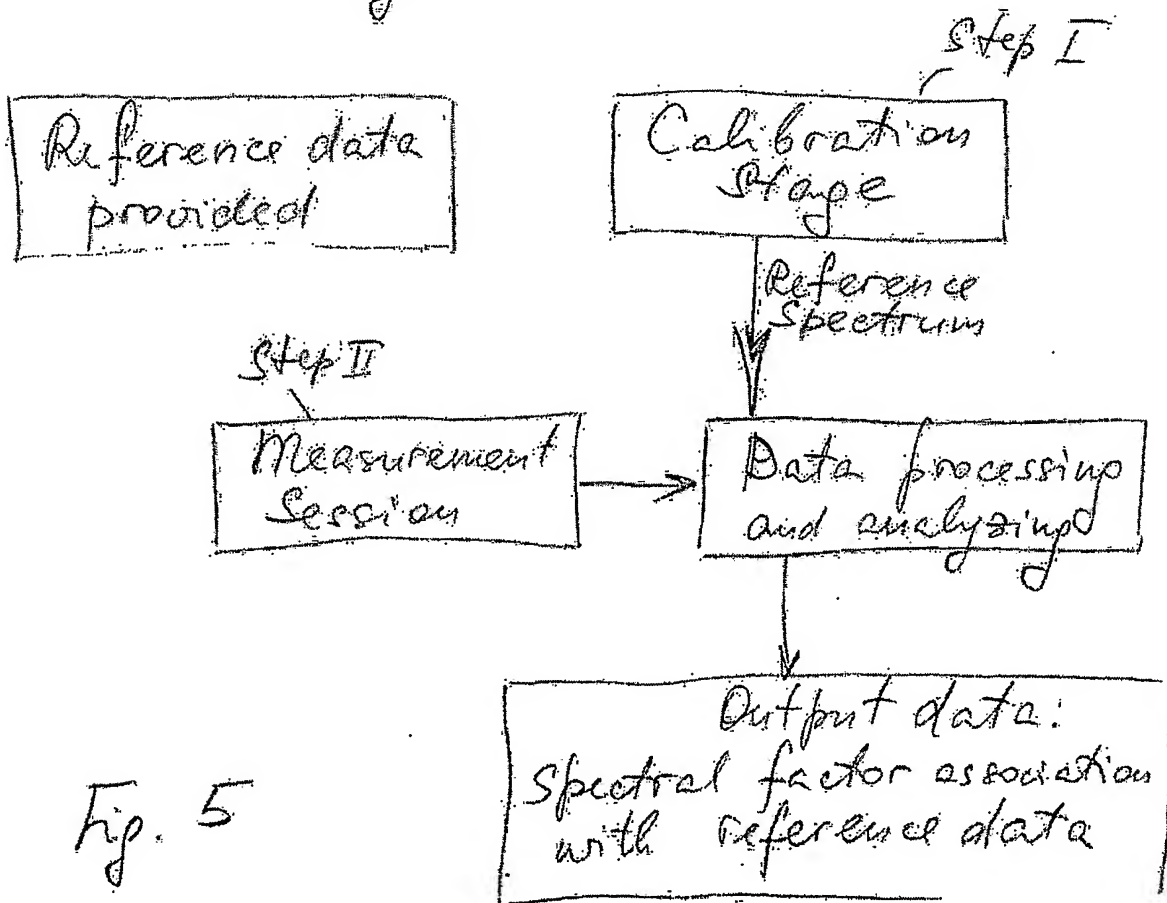


Fig. 5

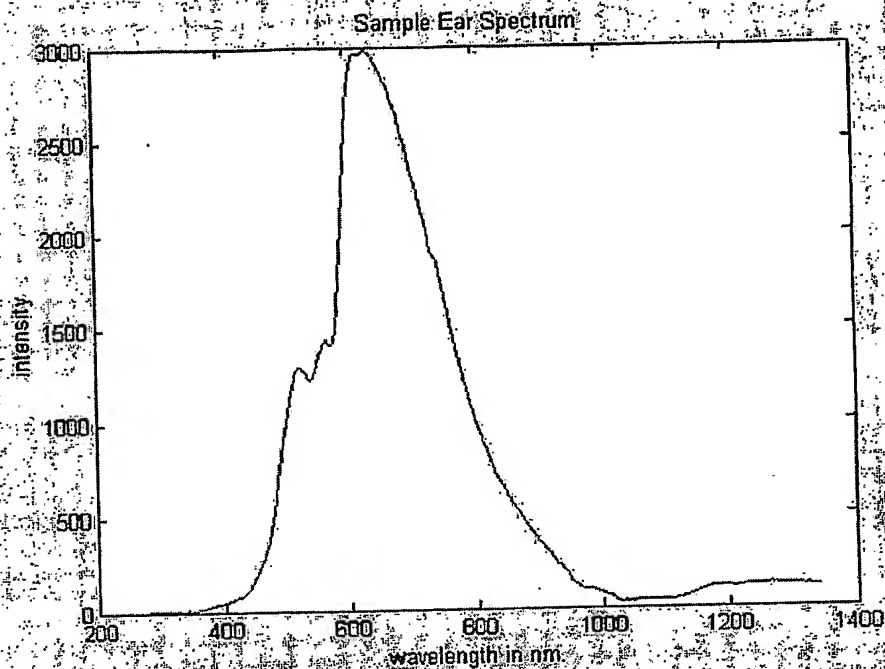


Fig. 6A

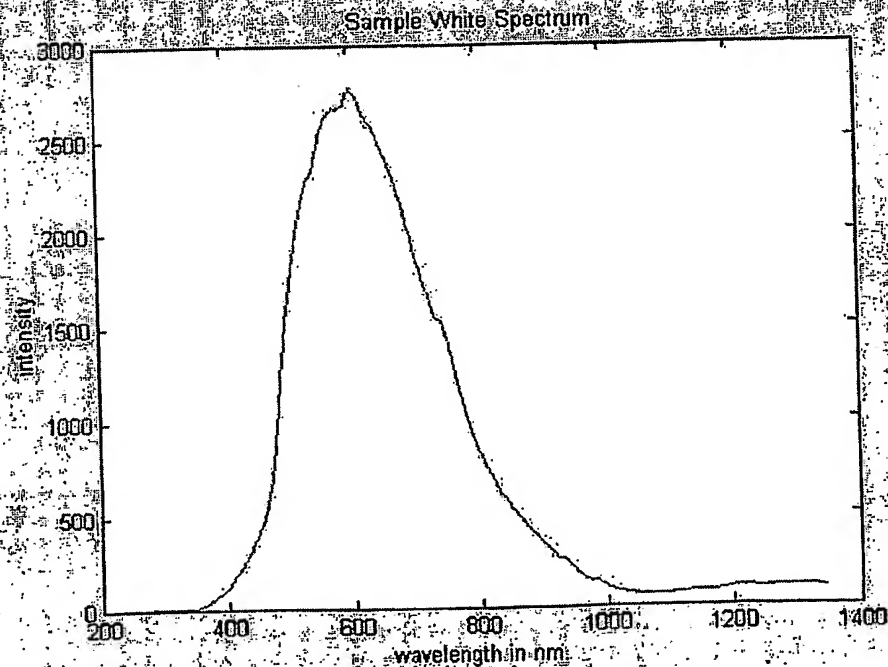


Fig. 6B

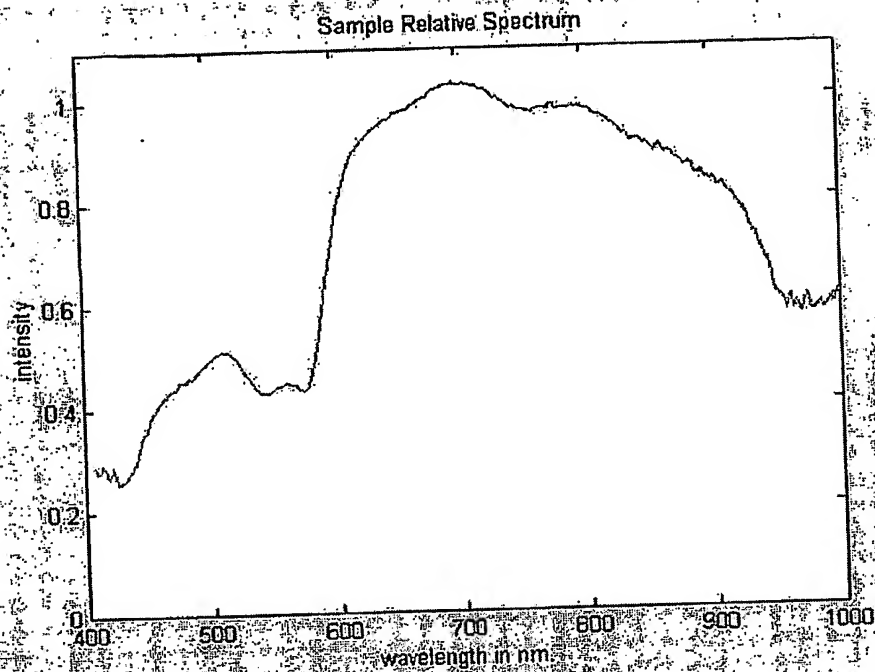


Fig. 6C

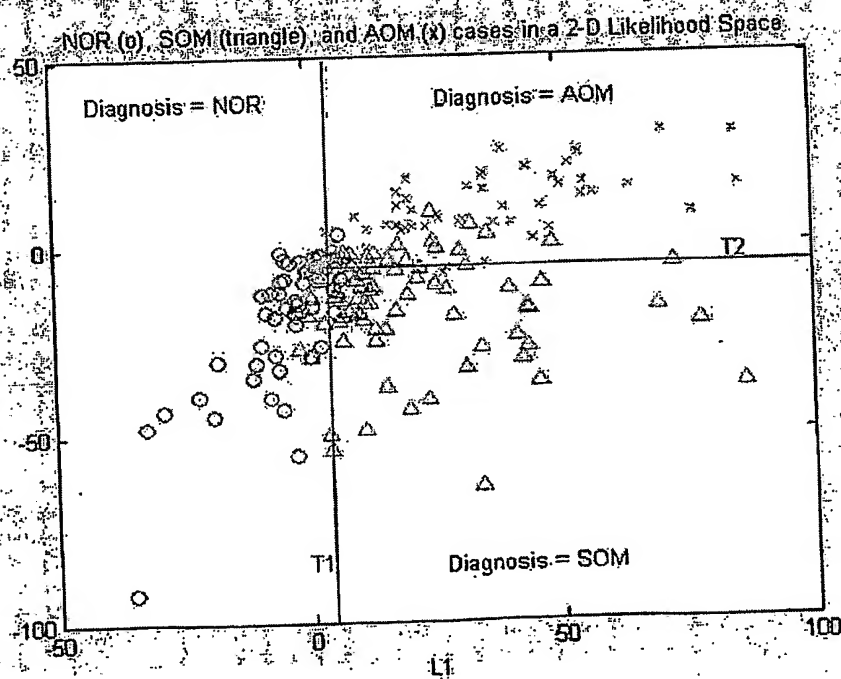


Fig. 6D